K090533

510(k) SUMMARY

DEC 18 2009

SUBMITTER:	Maquet Cardiopulmonary AG Hechinger Strasse 38 72145 Hirrlingen, Germany
CONTACT PERSON:	Dr. Ingrid Richter Phone: (011) 49 7478 921- 337 Fax: (011) 49 7478 921- 400
DATE PREPARED:	February 24, 2009
DEVICE TRADE NAME:	HLM Tubing Sets with Softline Coating
COMMON/USUAL NAME	Custom Tubing Pack
CLASSIFICATION NAME	Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing; Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting; Cardiopulmonary Bypass Pump Tubing.

PREDICATE DEVICES OR LEGALLY MARKETED DEVICES

HLM Tubing Set with Bioline coating (K080592)

Quadrox-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating (K082117)

DEVICE DESCRIPTION / INDICATONS FOR USE STATEMENT

The HLM Tubing Sets with Softline Coating are for single use only. They may be sold sterile, non-sterile, and bulk packed. Tubing sets that are sold sterile are not to be re-sterilized by the user.

In open heart surgery the HLM Tubing Sets with Softline Coating are used in combination with the heart-lung machine for the oxygenation of blood and removal of carbon dioxide. The main purpose of the HLM Tubing Sets with Softline Coating is to connect the patient to the heart-lung machine and its components. The HLM Tubing Sets with Softline Coating are therefore a

component in the extracorporeal perfusion circulation system. The utilization period of the use of the tubing sets is restricted to six hours.

The Softline Coating improves the physical surface properties of products for the extracorporeal circulation system.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The HLM Tubing Set – Softline Coated has the same intended use, design, principals of operation, and performance as the HLM Tubing Set with Bioline Coating. The only difference is the application of the Softline Coating instead of the Bioline coating to the set components.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Evaluation on safety and effectiveness was executed to demonstrate that the HLM-Tubing Set with Softline Coating described in this submission is substantially equivalent to the HLM-Tubing Set with Bioline Coating (K080592) as a custom tubing pack and to the Quadrox-i Adult Microporous Membrane Oxygenator with and without Integrated Arterial Filter with Softline Coating (K082117) with regards to the Softline Coating.

The following areas have been evaluated:

- Integrity
- Performance
- Biocompatibility
- Sterility

CONCLUSION

The data given demonstrate that the HLM-Tubing Set with Softline Coating is substantially equivalent to the named predicate devices which hold currently market clearance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Maquet Cardiopulmonary AG
c/o Dr. Ingrid Richter
Regulatory Affairs Manager
Hechinger Strasse 38
72145 Hirringen
Germany

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Re: K090533
HLM Tubing Set with Softline Coating
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DWF
Dated: November 23, 2009
Received: November 25, 2009

Dear Dr. Richter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090533

Device Name: HLM Tubing Set with Softline Coating

Indications for Use:

The HLM Tubing Sets with Softline Coating are designed to be used in extracorporeal circulation during cardiopulmonary bypass procedures lasting six hours or less.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

n Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090533

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(Posted November 13, 2003)